

**IN THE CLAIMS:**

**Please amend claim 26 as follows:**

26. (Thrice Amended) A method of ~~preventing~~ or treating a tumor in an animal which comprises administering to said animal a tumor inhibiting ~~effective amount~~ of an antigen-presenting cell, wherein said antigen presenting cell expresses at least one class I MHC or class II MHC ~~determinant~~ that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to said animal, and wherein said antigen-presenting cell is ~~transformed~~ with genomic DNA isolated from the tumor cells of said animal.

**REMARKS**

In the Final Action dated July 2, 2002, claims 26 and 41-46 are pending. Claims 26 and 41-46 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not supported by an enabling disclosure. Claim 43 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Payelle et al. (1981).

This Response addresses each of the Examiner's rejections. Applicant respectfully submits that the present application is in condition for allowance or at least in better condition for appeal. Favorable consideration of all pending claims is respectfully requested.

With respect to the rejection of claims 26 and 41-46 under 35 U.S.C. §112, first paragraph, these claims are directed to methods of preventing or treating cancer by administering to an animal an effective amount of a semi-allogeneic immunogenic cell, wherein said cell comprises an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic to the animal and at least one class I or class II

MHC determinant that is allogeneic to the animal, and wherein said antigen-presenting cell is transformed with genomic DNA isolated from the tumor cells of the animal.

Applicant previously submitted that the claimed methods are fully supported by the instant disclosure. Applicant pointed to some specific examples in the specification which illustrate the efficacy of the claimed methods. For example, the specification teaches the making of a fibroblast cell line of the H2-K<sup>k</sup> MHC class I determinant which is transfected with a gene coding for H2-K<sup>d</sup> MHC class I determinant, a DNA encoding IL-2, and genomic DNA from B16 (H2-K<sup>k</sup>) tumor cells. The specification further teaches that, by administering such semi-allogeneic transfected cells to mice, the injection of B16 tumor cells fails to establish any tumor mass in the animals. See, e.g., pages 50-53 of the specification, and in particular, the paragraph bridging pages 50-51 and Figure 2; and the paragraph bridging page 51-52 and Figure 3. Clearly, semi-allogeneic cells prepared in accordance with the present invention prevented the occurrence of a tumor in the subject animal. In addition, the specification teaches that semi-allogeneic cells prepared in accordance with the present invention also inhibited the growth of a pre-existing tumor in mice. See, e.g., pages 54-55 of the specification.

In the Final Action, the Examiner argued that the specification is not enabling because all the examples are drawn to methods of inhibiting tumor cell growth in mice. The Examiner states that the specification has not shown that tumor cells can be prevented in humans. The Examiner further states that one skilled in the art can not determine which members in the population would be in need of such prevention, because it is not known which individuals will be pre-disposed to the formation of tumors. The Examiner concludes that, until the methods for determining whether an individual is pre-disposed to the formation of tumors become available, methods used for the prevention of cancer cannot be envisioned.

Applicant respectfully submits that the claimed methods for preventing or treating a tumor in an animal employs an antigen-presenting cell that is semi-allogeneic and that is

transformed with genomic DNA isolated from the tumor cells of the animal. That is, the claimed methodologies are not directed to the general population at large, but to animals from which tumor cells are available for isolation of the genomic DNA. Therefore, one skilled in the art would know which individuals would be in need of an antigen-presenting cell that is semi-allogeneic and immunogenic.

Applicant further submits that the present specification provides adequate teaching for the instantly claimed methods. For example, the specification teaches isolation of genomic DNA from B16 melanoma cells, which are tumor cells from C57BL/6 mice. See page 48, Example 5. Semi-allogeneic antigen presenting cells, LM-IL-2K<sup>b</sup>, were transfected with the genomic DNA isolated from B16 melanoma cells. The transfected antigen presenting cells prevented and treated B16 melanoma in C57BL/6 mice, which are mice of the same strain as that from which B16 tumor cells were established and used to isolate the genomic DNA. See pages 50-53, Example 6 of the specification. Similarly, semi-allogenic antigen presenting cells (LM-IL-2K<sup>b</sup>), which were transfected with genomic DNA isolated from breast cancer cells (EO771), either completely prevented the occurrence or significantly suppressed the growth of tumor in C57BL/6J mice, which are mice of the same genetic background as the C57BL/6 mice from which the breast cancer cells (EO771) were derived. See pages 72-74, Example 15. Additionally, semi-allogenic antigen presenting cells (LM-IL-2K<sup>b</sup>), which were transfected with genomic DNA isolated from cells of a spontaneous breast adenocarcinoma arising in a C3H/He mouse, also significantly delayed the appearance of tumor and inhibited the growth of tumor in C3H/He mice. See pages 75-77, Example 16.

Applicant respectfully submits that the law does not require submission of human data in order to support the claimed invention under 35 U.S.C. § 112, first paragraph. Based on the present teaching, including the specific examples related to animals such as mice and the other general teachings provided in the specification, those skilled in the art would be able

to successfully practice the claimed methods in animal species such as human, to prevent or treat a tumor without undue experimentation.

Accordingly, it is respectfully submitted that the claimed methods are fully supported by an enabling disclosure. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

Claim 43 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Payelle et al. (1981).

Payelle et al. appear to teach the induction of protective T cells against a fibrosarcoma tumor (MCB6-1) by administering a hybrid cell made from fusing the fibrosarcoma (MCB6-1) to a fibroblast cell (A9). The hybrid cell appears to express both MHC class I and class II antigens.

It is respectfully submitted that claim 43 depends from claim 26. Claim 26, as presently amended, is directed to a method employing an antigen presenting cell which expresses at least one class I MHC or class II MHC determinant that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to said animal (i.e., the antigen presenting cell is semi-allogeneic), wherein the antigen-presenting cell is transformed with genomic DNA isolated from the tumor cells of the subject animal.

Applicant respectfully submits that Payelle et al. do not teach isolating genomic DNA from tumor cells, or transforming an antigen presenting cell with the isolated tumor genomic DNA. Therefore, Payelle et al. do not teach an antigen presenting cell transformed with the genomic DNA isolated from tumor cells, let alone a method of treating tumor with such antigen presenting cell. Therefore, Payelle et al. do not teach the claimed method. As such, withdrawal of the rejection of claim 43 under 35 U.S.C. §102(b) is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. I. Bernstein", with a long horizontal flourish extending to the right.

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Enclosure: Version with Markings to Show Changes Made

Serial No: 09/522,716  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

**Please amend claim 26 as follows:**

26. (Thrice Amended) A method of preventing or treating a tumor in an animal which comprises administering to said animal a tumor inhibiting effective amount of [a semi-allogeneic immunogenic cell, wherein said cell comprises] an antigen-presenting cell, wherein said antigen presenting cell expresses [expressing] at least one class I MHC or class II MHC determinant that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to said animal, and wherein said antigen-presenting cell is transformed with genomic DNA isolated from the tumor cells of said animal.